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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/879,445      | 06/11/2001  | Gregory R. Mundy     | OSTS:003USD2        | 4570             |

7590

07/06/2005

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EXAMINER

HOLLERAN, ANNE L

ART UNIT

PAPER NUMBER

1643

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/879,445

**Applicant(s)**

MUNDY ET AL.

**Examiner**

Anne Holleran

**Art Unit**

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 25,30 and 31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25,30 and 31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4/21/2005.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. The amendment filed April 6, 2005 is acknowledged.
2. Claim 25 was amended. Claims 25, 30 and 31 are pending and examined on the merits.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Objections and Rejections Withdrawn:***

4. The rejection of claims 25, 30 and 31 under 35 U.S.C. 102(b) as being anticipated by Liliemark (Liliemark, J., et al, Leukemia and Lymphoma, 4: 271-276, 1991) is withdrawn upon further consideration.

5. The rejection of claims 25, 30 and 31 under 35 U.S.C. 102(b) as being anticipated by Liliemark (Liliemark, et al, Leukemia and Lymphoma, 4: 271-276, 1991) as evidenced by Hotte (Hotte, S. J., et al., Am. J. Cancer 1(3): 179-187, 2002) is withdrawn upon further consideration.

#### ***New Grounds of Rejection:***

6. Claims 25, 30 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Spiers (Spiers, A.S.D., et al. Cancer 40: 20-29, 1977) as evidenced by Hibi (Hibi, S., et al. International Journal of Hematology 66: 3535-357, 1997).

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The claimed inventions are drawn to methods comprising the step of administering to a cancer patient having a cancer that expresses parathyroid hormone-related peptide (PTH-rP) a compound that is OSW3 or OSW6. The specification teaches that OSW6 is 6-thioguanine (page 8, description of Figure 5). The administration may be repeated, and the administration route may be oral or intravenous.

Spiers teaches treatment of patients with acute lymphoblastic leukemia (ALL) with 6-thioguanine (part of the TRAMPCOL Regimen). The administration was repeated (2 divided doses a day, at intervals of 12 hours. More than one course of treatment was administered. The administration was oral (see abstract, Table 1, page 21, and page 25). Hibi provides evidence that some patients with ALL express PTHrP (see abstract). Therefore, Spiers teaches a method that is the same as that claimed.

7. Claims 25, 30 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Konits (Konits, P.H. et al. Cancer Chemotherapy and Pharmacology, 8: 199-203, 1982) as evidenced by Malakouti (Malakouti, s. et al. The American Surgeon, 66(7): 540-544, 1996).

Konits teaches a method of treating colorectal cancer patients with 6-thioguanine (see abstract, page 200, page 202). The administration was repeated and was by the intravenous route. Malakouti provides evidence that in adenocarcinoma of the colon, in all cases studied, samples stained positive for PTHrP (see page 542, 1<sup>st</sup> column). Therefore, colon carcinoma is cancer that expresses PTHrP. Therefore, Konits teaches a method that is the same as that claimed.

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***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:30 pm.

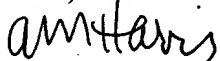
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran

Patent Examiner

June 29, 2005



**ALANA M. HARRIS, PH.D.  
PRIMARY EXAMINER**